IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA *ex rel.*; SUZANNE ALT, *et al.*, Plaintiffs, v. ANESTHESIA SERVICES ASSOCIATES, PLLC, *et al.*, Defendants.	Case No. 3:16-cv-0549; Case No. 3:16-cv-0561; Case No. 3:16-cv-1856; Case No. 3:19-cv-0102; Case No. 3:18-cv-0970 (consolidated) JUDGE TRAUGER

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT PETER KROLL MD'S PARTIAL MOTION TO DISMISS THE CONSOLIDATED COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA AND THE STATE OF TENNESSEE

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Dr. Peter Kroll moves to dismiss the claims in the Consolidated Complaint in Intervention ("Complaint") filed by the United States of America and the State of Tennessee (together, "the government") that are premised on allegations that Dr. Kroll violated the federal False Claims Act ("FCA") and Tennessee's equivalent by submitting—or having knowledge that other doctors were submitting—false claims for: urine drug tests ("UDT"); genetic testing to determine the rates at which a patient metabolizes specific drugs; and psychological testing to evaluate a patient's risk of addiction, depression, or suicidal thoughts.[1]

The government's FCA claims are premised upon alleged violations of Local Coverage Determinations ("LCDs") issued by Medicare Advantage Contractors ("MACs"), which are nothing more than interpretive guidance that do not go through formal rulemaking process. The U.S. Supreme Court recently held in *Azar v. Allina Health Services* that interpretive guidance does not bind healthcare providers unless promulgated through the notice-and-comment procedures required by the Medicare statute—which the LCDs were not. 139 S.Ct. 1804, 1813–15 (2019). Allegations of false certification of compliance with such guidance therefore cannot state a claim under the FCA.

Because the government cannot show that the testing at issue violated any binding requirements, it is left to rely on an amorphous notion of "medical necessity." But "liability for an FCA violation may not be premised on subjective interpretations of imprecise statutory language such as 'medically reasonable and necessary.'" *United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 2017 U.S. Dist. LEXIS 221356, at *20 (C.D. Cal. Dec. 29, 2017). Without controlling guidance promulgated through the notice-and-comment procedures required by the Medicare

[1] That is, Counts I–III as they pertain to the government's allegations of fraudulent schemes involving UDT, genetic testing under CPT code 81225, and psychological testing, and Counts I–IV to the extent they seek to impose vicarious liability on Dr. Kroll for allegedly fraudulent claims submitted by other CPS employees.

statute that defines "medical necessity" in a particular medical context, allegations of lack of medical necessity based on the supposed standard of care fail to state a claim under the FCA.

Nor does the government's Complaint state a claim against Dr. Kroll with respect to the allegations that ***other employees*** of the company at which Dr. Kroll was an owner/officer submitted false claims (i.e., the government's vicarious liability theory). The FCA contains a rigorous scienter requirement, which is not met by allegations of anything less than actual knowledge or deliberate ignorance or reckless disregard of the truth or falsity of the information submitted for payment. 31 U.S.C. § 3729(b)(1).

BACKGROUND

Dr. Kroll is a Medical Doctor who practices anesthesiology and interventional physical medicine and rehabilitation and he is board certified in both pain management and anesthesiology. Compl. ¶ 27. Dr. Kroll joined Anesthesia Services Associates, PLLC, d/b/a Comprehensive Pain Specialists ("CPS"), in August 2006, where he both treated patients full-time and served on the Board of Directors. *Id.* ¶¶ 27, 78, 88. CPS had been operational since 2000 and owned pain management clinics in several states. *Id.* ¶¶ 2, 75, 77, 82. Dr. Kroll became Chairman of the Board and President of CPS beginning September 30, 2015, and served as Chief Medical Officer from February 2016 until the company ceased operation. *Id.* ¶¶ 27, 88.

Dr. Kroll's patients come to him seeking relief from severe and chronic pain, often through referrals from other providers. *Id.* ¶¶ 27, 77. Because of the risk that his patients may abuse the medications used to manage their pain or may suffer adverse reactions from the interaction of medications or their dosages, Dr. Kroll regularly orders psychological testing to assess risks of abuse and addiction, UDT to detect the presence and levels of both prescribed and non-prescription medication, and sometimes orders genetic testing to determine whether a patient metabolizes a

pain management medication at a faster or slower rate than the general population. *Id.* ¶¶ 99, 213, 241.

The Complaint alleges that Dr. Kroll violated the FCA by falsely certifying that UDT testing, genetic testing, and psychological testing was medically necessary on claims that were submitted for payment by Medicare Part B, Medicaid (in which Tennessee participates through TennCare), TRICARE, and the Veteran's Association's CHAMPVA and Choice programs. *Id.* ¶¶ 33, 43–44, 47–48, 51–53. These public insurers cover "medically necessary" services such as provider visits, diagnostic tools, procedures, medical supplies, and durable medical equipment. *Id.* ¶¶ 34–35, 38–39, 60. Medicare, Medicaid, and TRICARE require providers to submit CMS Form 1500 with their reimbursement claims, which contains certifications that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment" and that the services "were medically necessary." *Id.* ¶¶ 64–65, 68. Likewise, TennCare, CHAMPVA, and Choice only pay for covered services that are medically necessary. *Id.* ¶¶ 61, 63.

LAW AND ARGUMENT

I. The Pleading Standards Unique to FCA Cases.

The government's FCA claims are subject to both Federal Rule of Civil Procedure 12(b)(6) and Rule 9(b). To avoid dismissal under the former, a complaint must contain specific factual allegations sufficient to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—that the pleader is entitled to relief." *Id.* at 679. The Court "need not accept as true legal conclusions or unwarranted factual inferences, and conclusory allegations or legal conclusions masquerading as factual allegations will not suffice." *Terry v. Tyson Farms, Inc.*, 604 F.3d 272, 276 (6th Cir. 2010).

FCA claims must also meet Rule 9(b)'s heightened pleading standard requiring particularity as to the circumstances constituting the alleged fraud. *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 501 F.3d 493, 503 (6th Cir. 2007). This means that the Complaint must specify the "'who, what, when, where, and how' of the alleged fraud." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006). "Courts are cautioned to construe false or fraudulent schemes as narrowly as necessary to protect the interests promoted by Rule 9(b)." *United States ex rel. Richardson v. Lexington Foot & Ankle Ctr. PSC*, 2018 U.S. Dist. LEXIS 93976, at *14 (E.D. Ky. June 5, 2018) (citing *Bledsoe*, 501 F.3d at 510).

"To state a claim under the FCA, the plaintiff must sufficiently plead: [1] that the defendant made a false statement or created a false record [2] with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information; [3] that the defendant . . . submitted a claim for payment to the federal government; . . . and [4] that the false statement or record was material to the Government's decision to make the payment sought in the defendant's claim." *United States ex rel. Sheldon v. Kettering Health Network*, 816 F.3d 399, 408 (6th Cir. 2016) (alterations omitted); *see also* 31 U.S.C. § 3729(a)(1)(A), (B), and (G). The "Tennessee Medicaid False Claims Act read[s] similarly and [is] substantively the same as the FCA," such that analysis of the government's FCA claims "appl[ies] equally" to the state-law claims. *United States ex rel. Nudelman v. Int'l Rehab. Assocs.*, 2006 U.S. Dist. LEXIS 17958, at *38-39 (E.D. Pa. Apr. 4, 2006); *see also* Tenn. Code Ann. § 71-5-182(a)(1)(A), (B), and (D).

The government alleges an express false-certification theory of FCA liability. (*See Chesbrough v. VPA. P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)). "In an express false certification, the defendant is alleged to have signed or otherwise certified to compliance with some law or regulation on the face of the claim submitted." *United States ex rel. Hobbs v. Medquest Assocs.*,

711 F.3d 707, 714 (6th Cir. 2013). A false-certification theory "only applies where the underlying regulation is a 'condition of payment,' meaning that the government would not have paid the claim had it known the provider was not in compliance." *Id.* And in evaluating a false certification claim, "[c]ourts do not look to the claimant's actual statements; rather, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *Id.* (quotations omitted).

Applying these standards, the Complaint fails to state a claim under the FCA against Dr. Kroll for his UDT testing, his genetic testing billed under CPT code 8122, or his psychological testing, and fails to state a claim against Dr. Kroll under the FCA to the extent the government is premising Counts I-IV upon a theory of Dr. Kroll's vicarious liability for the conduct of others.

II. The Government Cannot State an FCA Claim Based on Alleged Noncompliance with Subregulatory Guidance.

Medicare is "a massive, complex health and safety program . . . embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 13 (2000). Yet the government's allegations in this case are not premised on purported noncompliance with any statute or regulation. Instead, the government alleges that the claims for UDT and genetic testing billed under CPT code 8122 were "false" because they allegedly were inconsistent with LCDs issued by MACs. This theory cannot be squared with recent Supreme Court precedent holding that both "substantive" and so-called "interpretive" standards governing Medicare reimbursement must be promulgated via notice-and-comment rulemaking in order to bind providers or have the force of law. *Allina*, 139 S. Ct. at 1817. Because the LCDs upon which the government here tries to stake FCA liability were not promulgated via notice-and-comment rulemaking, the government cannot state an FCA claim based on these LCDs.

A. The Medicare Act, National Coverage Determinations, and LCDs.

The Medicare Act provides that no payment may be made to a physician under Medicare Part B if the items or services are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Consequently, in order to obtain Medicare reimbursement, providers must make certifications relating to the services they have provided to patients—including a certification of medical necessity. (*See* 42 U.S.C. § 1395f(a)(2)–(3).) In practical terms, when submitting CMS Form 1500 for payment under the Medicare program, a physician must certify that, among other things, "the services on this form were medically necessary" and that the provider was familiar "with all applicable laws, regulations, and program instructions." Compl. ¶ 65.

The Department of Health and Human Services ("HHS") decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The former course involves a National Coverage Determination ("NCD"). Through NCDs, HHS announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). Under the current statute, HHS is required to use notice-and-comment procedures to promulgate NCDs—allowing at least 30 days for public comment before a final decision is made. 42 U.S.C. § 1395y(l)(3); *see also* 78 Fed. Reg. 48,164 (Aug. 7, 2013). NCDs are binding and have the force of law. (*See* 42 C.F.R. § 405.1060; *see also United States v. Adams*, 371 F. Supp. 3d 1195, 1213 (N.D. Ga. 2019) ("NCDs are considered substantive rules, which carry the force of law.")).

In the absence of an NCD, whether services are reasonable and necessary is determined by local MACs.[2] A MAC may issue an LCD, which announces "whether or not a particular item or

[2] CMS's MAC for Tennessee and Alabama was Cahaba Government Benefit Administrators from 2011 to February 25, 2018, and Palmetto Government Benefit Administrator thereafter. (*Id.* ¶¶ 40, 187.)

service is covered" by that particular contractor. 42 U.S.C. § 1395ff(f)(2)(B). By statute, LCDs must be published on the contractor's website for a minimum of 45 days before they become effective. 42 U.S.C. § 1395y(l)(5)(D). Otherwise, however, LCDs are quite different from NCDs because: (a) they are not subject to formal notice-and-comment procedures; (b) they do not apply at all beyond the individual contractor that has adopted them; and (c) they are not binding on the agency. *See* 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003).

B. The Supreme Court's recent ruling in *Azar v. Allina Health Services* means FCA suits based on alleged noncompliance with LCDs fail to state a claim.

To understand the impact of *Azar v. Allina Health Services*—a landmark decision issued three months ago in which the Supreme Court held that even so-called "interpretive" guidance on Medicare reimbursement must go through formal rulemaking to be valid, 139 S. Ct. 1804, 1810 (2019)—one must review earlier lower-court decisions that allowed FCA claims based on alleged noncompliance with LCDs to survive the pleading stage. Until *Allina*, some courts assumed based on the "very limited case law on the question" that the submission of "claims that are contrary to an LCD can—under certain circumstances—give rise to FCA liability for non-compliance."[3] *United States v. Sklar*, 273 F. Supp. 3d 889, 896 (N.D. Ill. 2017) (holding that "LCDs are binding" on healthcare providers). These courts likened LCDs to "agency interpretations contained in policy statements, manuals, and enforcement guidelines" that, while "not entitled to the force of law," can be "conclusive as to matters that they address[]." *Adams*, 371 F. Supp. 3d at 1213 (citing *United States ex rel. Ryan v. Lederman*, 2014 U.S. Dist. LEXIS 65666, at *12 (E.D.N.Y. May 13, 2014)). They rejected the notion that "LCDs are advisory or not authoritative" and instead treated

[3] Even before *Allina*, other courts doubted that conclusion. *See, e.g., United States ex rel. McMullen v. Ascension Health*, No. 3-12-0501, 2013 U.S. Dist. LEXIS 163739, at *6 n.3 (M.D. Tenn. Nov. 18, 2013) (calling into question whether LCDs "issued by contractors, not by the Government," can bind providers for FCA purposes, and noting that the relator "d[id] not cite to a statute or regulation that conditions payment of a Medicare claim on compliance with any LCD").

them as "gap-fillers" to be used "where there [are] no national rule[s]" that are "mandatory for the areas they cover." *Lederman*, 2014 U.S. Dist. LEXIS 65666, at *11–13. Based on that supposition, these courts allowed alleged noncompliance with LCDs to serve as a basis for liability under the FCA. (*See, e.g.*, *id.* at *15; *Sklar*, 273 F. Supp. 3d at 897–98.)

This assumption that noncompliance with an LCD could trigger FCA liability rested upon on another assumption: that LCDs could be treated as binding on providers without having been promulgated through the notice-and-comment statute that Congress drafted specifically for Medicare in 1987. That statute provides:

> ***No rule, requirement, or other statement of policy*** (other than a national coverage determination) that ***establishes or changes a substantive legal standard governing*** the scope of benefits, the ***payment for services***, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title ***shall take effect unless it is promulgated*** by the [HHS] Secretary ***by regulation*** [via notice-and-comment rulemaking].

42 U.S.C. § 1395hh(a)(2) (emphases added). For years, lower courts surmised that this provision mirrors the Administrative Procedure Act ("APA"), such that—while "substantive" rules must be promulgated via notice and comment—so-called "interpretive" rules need not.[4] *See, e.g.*, *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 2011 U.S. Dist. LEXIS 61947, at *31 (C.D. Ill. June 7, 2011) ("The courts that have considered this issue have concluded or assumed without deciding that Section 1395hh imposes no standards greater than those established by the APA.").

But in *Allina*, the Supreme Court held that this assumption is ***wrong***: Section 1395hh(a)(2) is broader than the APA and requires even so-called "interpretive" guidance to go through formal rulemaking to be valid. 139 S. Ct. 1804, 1810 (2019). In *Allina*, a group of hospitals argued that

[4] "Interpretive rules are those which merely clarify or explain existing law or regulations." *Your Home Visiting Nurse Servs. v. Sec'y of HHS*, 132 F.3d 1135, 1139 (6th Cir. 1997). The APA "exempts interpretive rules from its notice and comment requirements." *Id.*

the government violated the Medicare Act by announcing a new policy on "Medicare fractions" concerning care provided to low-income patients without proceeding through notice and comment. *Id.* at 1810. The government "admitted that it hadn't provided notice and comment but argued it wasn't required to do so in these circumstances" because the new policy amounted only to an "interpretive legal standard" (as opposed to a substantive one) "that merely advise[d] the public of the agency's construction of the statutes and rules which it administers." *Id.* at 1810–11 (emphasis and quotations omitted). But the Court ruled that "[t]he government's interpretation can't be right" because the Medicare Act "doesn't use the word 'substantive' in the same way the APA does—to identify only those legal standards that have the 'force and effect of law.'" *Id.* at 1811. Rather, the Medicare Act's conception of "substantive legal standards" is broader than the APA's, such that even so-called interpretive rules must be promulgated via notice and comment. *Id.* at 1813–15.

C. The Complaint's allegations about UDT and genetic testing billed under CPT code 8122 allege only noncompliance with LCDs.

As stated, the federal healthcare programs and TennCare provide reimbursement for UDT when it is "medically necessary." *Id.* ¶ 99. The government's understanding of when UDT is medically necessary is a moving target. The Complaint vaguely refers to "[c]ommon practice in the medical community" (*id.* ¶ 100), "Medicare rules" without citation to any rules (*id.* ¶ 103), and what the federal healthcare programs and TennCare "generally require" without citation to any requirements (*id.* ¶ 104). Ultimately, the government hangs its hat on LCDs issued by MACs, none of which were subject to notice-and-comment rulemaking. These include:

- An October 2015 Cahaba LCD stating that routine, per-patient UDT is noncovered. *Id.* ¶ 107.
- A June 2015 Cahaba LCD stating that while "[r]outine standing orders for all patients in a physician's practice are not reasonable and necessary," "[p]hysician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary." *Id.* ¶¶ 108–09.

- Palmetto's LCD from when it replaced Cahaba in 2018, which divided patients into risk categories and stated that low-risk patients should be randomly tested 1–2 times every year, moderate-risk patients 1–2 times every six months, and high-risk patients 1–3 times every three months. *Id.* ¶¶ 111, 187.

At bottom, the Complaint alleges that Dr. Kroll's and CPS' UDT policies and practices "did not comply with the requirements of the various MACs and lacked medical necessity." *Id.* ¶ 145.

The Complaint also alleges that CPS and Dr. Kroll engaged in medically unnecessary genetic testing. Here, too, the government relies on LCDs to allege lack of medical necessity. Specifically, the Complaint invokes an October 2015 Cahaba LCD stating that genetic testing is only covered as medically necessary under CPT code 81225 if the patient has acute coronary syndrome and has been undergoing percutaneous coronary interventions with Plavix therapy.[5] *Id.* ¶ 216. The Complaint alleges that Dr. Kroll and other providers excessively billed for genetic testing that was not medically necessary under this code. *Id.* ¶ 239.

D. The government's cited subregulatory guidance cannot support FCA liability for UDT or psychological testing billed under CPT code 81225.

If the LCDs on which the government relies were to have controlling effect in the FCA context, then under *Allina* they were required under Section 1395hh(a)(2) to have been promulgated via notice and comment. That provision requires such rulemaking for any: (1) "rule, requirement, or other statement of policy" that; (2) "establishes or changes"; (3) a "substantive legal standard" that; (4) governs "payment for services." 42 U.S.C. § 1395hh(a)(2). Because the LCDs that the government seeks to use as the basis for Dr. Kroll's FCA liability were not promulgated via notice and comment despite these four elements being present, the government's FCA counts premised on these LCDs fails to state a claim.

[5] The Complaint also notes that a "Wisconsin Physician Service [LCD] also provided for similar limited use." (Compl. ¶ 216.) CPS did not operate any clinics in Wisconsin. (*Id.* ¶ 82.)

The LCDs the government cites clearly purport to be: rules of interpretation (*Adams*, 371 F. Supp. 3d at 1213); requirements "command[ing]" certain practices (*Allina Health Servs. v. Price*, 863 F.3d 937, 943 (2017), *aff'd Allina*, 139 S. Ct. 1804 (2019)); or statements of policy announcing the MACs' approaches to the issues addressed by the LCDs (*Allina*, 139 S. Ct. at 1810). *See, e.g.*, Compl ¶ 111 ("Palmetto's LCD 35724 . . . ***required*** providers to engage in a patient-specific risk analysis to determine how often UDT should be performed on patients." (emphasis added)).

And each LCD at issue either established or changed standards imposed on providers. (*See, e.g.*, *id.* ¶¶ 108, 112.) Those standards plainly governed "payment for services" because they set forth allowable treatment and billing practices as well as those that were "noncovered." (*Id.* ¶ 107.) *See also* 42 U.S.C. § 1395ff(f)(2)(B) (defining LCD as "a determination by a fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis").

That leaves the "substantive legal standard" question—which *Allina* answers. Supposing LCDs are best understood as "interpretive" rules (albeit with binding, conclusive effect) (*see Adams*, 371 F. Supp. 3d at 1213), they still establish ***substantive*** legal standards under Section 1395hh(a)(2). "LCDs are gap-fillers" through which a local contractor "make[s] its own rules" in the absence of a national rule. *Lederman*, 2014 U.S. Dist. LEXIS 65666, at *11. And under *Allina*, "when the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under §1395hh(a)(2)." 139 S. Ct. at 1817. Put differently, as explained in the D.C. Circuit decision affirmed by the Supreme Court in *Allina*, a "'substantive legal standard' at a minimum includes a standard that 'creates, defines, and regulates the rights, duties, and powers of parties.'" *Allina*, 863 F.3d at 943 (quoting Black's Law Dictionary (10th ed.

2014)). Because the LCDs at issue "define the scope of [providers'] legal rights to payment" for services deemed medically reasonable and necessary (*id.*), they embody substantive legal standards that require notice-and-comment rulemaking to "take effect". (42 U.S.C. § 1395hh(a)(2)). The LCDs on which the government relies were not promulgated in accordance with Section 1395hh(a)(2) and thus have no controlling effect on providers.

In sum, the government's FCA claims with respect to UDT and genetic testing under CPT code 81225 are not premised on failure to comply with a statutory or regulatory requirement—or ***any*** "substantive legal standard" properly promulgated through notice-and-comment rulemaking under Section 1395hh(a)(2). These claims therefore fail as a matter of law.

What makes the government's lawsuit all the more stunning is that it also is improper as a matter of official policy. The Department of Justice forbids its litigators from using alleged noncompliance with subregulatory guidance "as a basis for proving violations of applicable law" in civil enforcement cases, including "when the Department is enforcing the False Claims Act, alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements." *See* Mem. from Assoc. Att'y Gen. to Heads of Civil Litigating Components and U.S. Att'ys, at 1 n.1, 2 (Jan. 25, 2018).[6] This is because, according to DOJ's official view, "[g]uidance documents cannot create binding requirements [under the FCA] that do not already exist by statute or regulation." *Id.* at 2.

The government was and remains free to elaborate on medical necessity as it applies to UDT and genetic testing under CPT code 81225 through an NCD or formal notice-and-comment rulemaking. But it has instead punted the decision to private contractors. Under *Allina*, that choice to forego public notice and input has consequences. *See Medquest*, 711 F.3d at 718–19 ("[T]he

[6] Available at https://www.justice.gov/file/1028756/download (last accessed Sept. 11, 2019).

FCA does not impose liability for providers' failure to anticipate needs of the program that have not been promulgated in regulations conditioning payment on compliance, in addition to providers' obligations to navigate the already-complicated scheme of regulations.").

III. The government's allegations of lack of medical necessity for UDT, genetic testing under CPT code 81225, and psychological testing do not state a claim under the FCA.

As discussed above, the government cannot premise its FCA claims on subregulatory guidance not promulgated consistent with Section 1395hh(a)(2) of the Medicare Act. That leaves the government with the bare assertion in its Complaint that the testing at issue was not medically "reasonable and necessary." *See* Compl. ¶¶ 60, 62–63, 65, 68. But, as a matter of law, the allegations in the Complaint, even if proven, cannot support a finding that this testing was medically unnecessary and therefore false.

A fraudulent claim is the "*sine qua non* of a False Claims Act violation." *Sanderson*, 447 F.3d at 878. Accordingly, the government must establish that Dr. Kroll submitted claims that he knew were ***objectively*** false. *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc*, 114 F. Supp. 3d 549, 566 (E.D. Tenn. 2014) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."). "Ordinarily, facts are the only item that fits in this category; opinions—when given honestly—are almost never false." *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018).

A. The government cannot state an FCA claim based on lack of medical reasonableness and necessity in the absence of a controlling statutory or regulatory instruction.

"[L]iability for an FCA violation may not be premised on subjective interpretations of imprecise statutory language such as 'medically reasonable and necessary.'" *Gardens*, 2017 U.S. Dist. LEXIS 221356, at *20; *see also Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001) ("The term 'medical necessity' does not impart a qualitative element mandating a particular standard of

medical care."). Without some controlling guidance situating that phrase to a particular medical context, FCA liability cannot follow. (*See, e.g.*, *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1031–32 (D. Nev. 2006) (holding that the defendant provider's claims "cannot be false, as a matter of law, because . . . the Government has not established any violation of a controlling rule, regulation, or standard in Defendants' provision of [medical services]" and there was no "governing L[CD] setting forth the precise [requirements]")). Oblique references to "[c]ommon practice in the medical community," (Compl. ¶ 100), or the general policies of "private insurers" (*id.* ¶ 244), are not a proper substitute. (*See, e.g.*, *Chesbrough*, 655 F.3d at 468 ("Medicare does not require compliance with an industry standard as a prerequisite to payment. Thus, requesting payment for tests that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA."); *Gardens*, 2017 U.S. Dist. LEXIS 221356, at *6, 20–21 (explaining that relator could not "equate" a privately issued set of hospital industry standards on the "medical appropriateness of hospital admission" with "the medical necessity standard imposed by Medicare" to establish that certifications of medical necessity were "objectively false")). Nor can open-ended allegations about what "Medicare rules" and government health programs "generally require" (Compl. ¶¶ 103–04) establish objective falsity where the government "identif[ies] no specific Medicare or Medicaid regulation that mentions the standards." *Chesbrough*, 655 F.3d at 468.

With no controlling rule on point, the government's FCA theory regarding Dr. Kroll's conduct as a medical provider amounts to inappropriate—and legally insufficient—second guessing of the medical judgment exercised by Dr. Kroll. The testing that the government challenges as medically unreasonable and unnecessary is geared toward assessing the propriety, safety, and potential risks of prescribing potent drugs to pain patients. Compl. ¶¶ 98–99, 213, 241.

The government cannot substitute the medical judgment occasioned by such testing decisions with its own ethereal conception of what is medically "reasonable and necessary." Much like questions of medical judgment regarding the appropriateness of hospital admissions (which involve medical assessment of the "severity" of patients' conditions), the "subjective medical opinions" at issue in determining whether and how frequently to test a patient for the appropriateness of pain medication "cannot be proven to be objectively false"—at least not in the absence of a controlling rule, regulation, or standard to guide that medical judgment. (*Gardens*, 2017 U.S. Dist. LEXIS 221356, at 20–21. *See also, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011) ("[A] physician must use his clinical judgment to determine hospice eligibility, and an FCA complaint about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of subjective clinical analysis."); *United States v. AseraCare, Inc.*, 2019 U.S. App. LEXIS 27074, at *43 (11th Cir. Sep. 9, 2019) (holding that a provider's submission of a claim making a certification based on the provider's "clinical judgment . . . cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood," even if "a different physician later contends that the judgment is wrong")).

Finally, with respect to psychological testing, the government accepts that such testing is reimbursable "if it is medically necessary under CPT code 96103," but asserts that "Defendants knew or should have known that the type of testing CPS and its providers were performing was not reimbursable." *Id.* ¶ 243. The Complaint, however, does not cite to any statutory, regulatory, or even subregulatory construction of "medical necessity" to that effect. Rather, the government claims that "***private*** insurers did not reimburse for psychological testing performed on an iPad by a provider that was not treating mental health issues." *Id.* ¶ 244 (emphasis added). The Complaint

fails to identify any specific, controlling standard whatsoever with respect to its psychological testing allegations. (*See* Compl. ¶¶ 242–44.) That dooms the government's claims with respect to those categories of tests.

B. The Complaint does not allege particularized facts showing objectively false certifications with UDT-related LCDs.

Even if noncompliance with an LCD could support FCA liability—which it cannot—the Complaint alleges that certain alleged CPS policies were illegal as evidenced by LCDs that ***post-date*** the alleged policies. (*See* Compl. ¶¶ 126, 130–36.) The government cannot support FCA liability for claims preceding mid-2015 without supplying some controlling standard rendering them objectively false at the time they were made. (*See, e.g.*, *Prabhu*, 442 F. Supp. 2d at 1031–32.)

Separately, the Complaint acknowledges that, as early as September 1, 2015, Dr. Kroll was involved in a series of efforts to revise CPS's UDT policies to emphasize individualized patient risk. *See infra*, pp 17-19. This was so even though the only LCD cited by the Complaint that mentions patient risk stratification did not become operative for CPS until February 2018. *See infra*, n. 2, 10. The government attempts to dismiss these compliance efforts by asserting that "internal practices regarding standing orders for UDT remained largely unchanged throughout this time period," (Compl. ¶ 180), but it does not provide particularized factual allegations in support of its say-so.[7] Still further, "[t]o establish falsity under the FCA, it is not sufficient to demonstrate that the person's practices could have or should have been better." *Prabhu*, 442 F. Supp. 2d at 1032–33.

[7] The same is true for the Complaint's factually unsupported assertions that Dr. Kroll "was still in favor of standing orders that did not emphasize individual patient risk" and "was still pushing UDT" in 2018. (Compl. ¶¶ 180, 186.) Moreover, those claims are hard to square with the Complaint's factual allegations that Dr. Kroll ***approved*** a series of 2015-and-later UDT policy revisions providing for risk stratification. (*See, e.g., id.* ¶¶ 158, 166.)

Finally, the government repeatedly invokes CPS's UDT "standing order" form. But, as indicated by the spliced-together snippets of an October 2014 email exchange that the government cites in the Complaint, this form was essentially a ***template*** for providers to mark-up and fill-out. Compl. ¶ 131. "Pre-populated forms," or "templates," "are not uncommon in medical practice," and while the government makes much of their mere existence in this case, it does not provide "concrete example[s] of how the form was misused." *Richardson*, 2018 U.S. Dist. LEXIS 93976, at *16–17.

IV. The Government's Vicarious Liability Theory Is Insufficient to Hold Dr. Kroll Liable for Allegedly False Claims Submitted by Other CPS Employees.

The Complaint seeks to hold Dr. Kroll liable for purportedly false claims that he himself allegedly submitted, but it does not stop there. It also seeks to hold him liable for ***all*** allegedly false claims submitted by CPS personnel throughout Dr. Kroll's tenure based on Dr. Kroll's ownership interest and leadership positions. (Compl. ¶¶ 27, 88, 364, 366, 378.) The FCA does not permit this sweeping extension into vicarious liability.

The FCA contains a "rigorous" scienter requirement. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). A person only "knowingly" submits a false claim or record if he does so with "actual knowledge" or acts in either "deliberate ignorance" or "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). "Although the 'deliberate ignorance' and 'reckless disregard' standards are intended to prevent senior executives from insulating themselves from the fraudulent activity of subordinates, the FCA does not make senior executives strictly liable for all false claims submitted by a company." *United States ex rel. Davis v. Prince*, 2011 U.S. Dist. LEXIS 77152, at *16–17 (E.D. Va. June 23, 2011). Nor does it permit liability on the basis of mere "negligent" oversight. *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc*, 114 F. Supp. 3d 549, 567 (E.D. Tenn.

2014). Rather, these standards "target that defendant who has 'buried his head in the sand' and failed to make some inquiry into the claim's validity." *Williams*, 696 F.3d at 530.

The Complaint fails to put forth sufficient allegations to establish that Dr. Kroll acted with actual knowledge of false claims purportedly submitted by other CPS employees. The government's principle line of attack in this regard is that Dr. Kroll was "aware" of the 2014 external audit of CPS and "had knowledge of the daily activities of CPS providers" and the activities of CPS's compliance committee. (Compl. ¶¶ 365, 378.)

There are several problems with the government's approach. First, any after-the-fact awareness of potential billing issues acquired by Dr. Kroll in these capacities is insufficient to establish actual knowledge of falsity at the time the claims were made. (*See, e.g.*, *In re Omnicare, Inc. Sec. Litig.*, 2013 U.S. Dist. LEXIS 42973, at *33-34 (E.D. Ky. Mar. 27, 2013) (holding that sharing of audit results with two executives was on its own "insufficient to establish actual knowledge" of falsity of statements of legal compliance); *United States ex rel. Sheldon v. Kettering Health Network*, 2015 U.S. Dist. LEXIS 803, at *11 (S.D. Ohio Jan. 6, 2015)). Second, these allegations certainly do not establish that Dr. Kroll "buried his head in the sand" (*Williams*, 696 F.3d at 530), much less "fail[ed] to take reasonable steps" to ensure that CPS was submitting valid claims. *United States v. Stevens*, 605 F. Supp. 2d 863, 867 (W.D. Ky. 2008) (citing *United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997)). To the contrary, the Complaint details Dr. Kroll's multiple, successive efforts to ensure that UDT policies and practices were compliant—including by approving revised UDT guidance providing for individualized risk assessment and by personally providing additional training for the personnel "primarily" responsible for the claims subject to the external audit in order to ***prevent*** any improper billing. (*See, e..g.*, Compl. ¶¶ 158, 161, 163–66, 170, 181.) And, as the Complaint concedes, "most of the [claim] denials" that

resulted from the initial audit were reversed after CPS and Dr. Kroll submitted corrected dates of service and letters of medical necessity. *Id.* ¶¶ 176–77. In short, far from alleging facts showing that Dr. Kroll "turned a blind eye" to alleged noncompliance (*id.* ¶ 366), the Complaint acknowledges the steps taken by Dr. Kroll to ensure compliance, and merely posits—without supporting facts—that he had some hidden, improper motive. (*e.g.*, *id.* ¶¶ 180, 186.) That is not enough. (*See, e.g.*, *United States ex rel. Farmer v. City of Hous.*, 523 F.3d 333, 339 (5th Cir. 2008) ("Given [the FCA's] definition of 'knowingly,' courts have found that the mismanagement . . . of programs that receive federal dollars is not enough to create FCA liability.")).

The government's remaining scienter allegations in support of vicarious liability are even weaker. The fact that Dr. Kroll "had an ownership interest" in CPS is simply "irrelevant to h[is] liability under the FCA." *United States ex rel. Doe v. Heart Sol., PC*, 923 F.3d 308, 314 (3d Cir. 2019). Likewise, the government's hyper-emphasis on CPS's profit motive (*e.g.*, Compl. ¶¶ 190–97, 367–72), is a red herring. (*See Williams*, 696 F.3d at 529 ("[T]he United States focuses, somewhat obsessively, on evidence demonstrating that [defendant company] sought . . . reimbursements for the sole purpose of increasing its profit margins. Why a business ought to be punished [under the FCA] solely for seeking to maximize profits escapes us.")). Nor can the government impute the alleged knowledge or reckless disregard of other CPS executives to Dr. Kroll. (*See, e.g.*, *City of Morristown v. BellSouth Telecomms., LLC*, 206 F. Supp. 3d 1321, 1338 (E.D. Tenn. 2016) ("Rule 9(b) does not permit a plaintiff to allege fraud by indiscriminately grouping all of the individual defendants into one wrongdoing monolith." (quotations omitted))).

Finally, and separately, the government cannot establish Dr. Kroll's knowledge of the alleged falsity of either his own or other employees' claims concerning UDT, genetic testing under CPT code 81225, or psychological testing for an additional reason: "no rule or regulation expressly

prohibited billing" for those claims. *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 145 F. Supp. 3d 1220, 1260 (N.D. Ga. 2015), *rev'd on other grounds*, 841 F.3d 927 (11th Cir. 2016). (*See supra*, 17-18.)

In sum, "[t]his is . . . not a case of a defendant receiving the benefit of clear regulations or a clear, authoritative warning from the government that [his] conduct might be unlawful and failing to take appropriate action." *Id.* at 1263–63. Dr. Kroll therefore "could not have acted with the knowledge that the FCA requires." *United States ex rel. Hixson v. Health Mgmt. Sys.*, 613 F.3d 1186, 1190 (8th Cir. 2010).

RELIEF REQUESTED

Dr. Kroll respectfully requests that the Court dismiss: (i) Counts I–III of the Complaint as they pertain to the government's allegations of fraudulent schemes involving UDT, genetic testing, and psychological testing; and, (ii) Counts I–IV to the extent they seek to impose vicarious liability on Dr. Kroll for allegedly fraudulent claims submitted by others. Because the government has had more than three years to investigate and develop its case since the filing of the first *qui tam* complaint, Dr. Kroll submits that the dismissal should be with prejudice.

Respectfully submitted,

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/s/ Daniel J. Martin

Daniel J. Martin (admitted *pro hac vice*)
JONES WALKER LLP
420 20th St N, Suite 1100
Birmingham, AL 35203
Tel: (205) 244-5200
Fax: (205) 244-5400
danielmartin@joneswalker.com

Michael W. Magner (admitted *pro hac vice*)
Avery B. Pardee (admitted *pro hac vice*)
Michael J. O'Brien (admitted *pro hac vice*)
JONES WALKER LLP
201 St. Charles Avenue
New Orleans, LA 70170
Tel: (504) 582-8000
Fax: (504) 582-8583
mobrien@joneswalker.com

Counsel for Defendant Peter Kroll, M.D.

CERTIFICATE OF SERVICE

I hereby certify that on this day I caused a true and correct copy of the foregoing document to be filed via the Court's CM/ECF system, which will send notification of such filing to the following:

Kara F. Sweet
U.S. Attorney's Office
Middle District of Tennessee
110 Ninth Avenue S, Suite A-961
Tel: (615) 736-5151
Fax: (615) 401-6626
Kara.Sweet@usdoj.gov

Counsel for Plaintiff United States of America ex rel.

Philip H. Bangle
Tennessee Attorney General's Office
P.O. Box 20207
Nashville, TN 37202
Tel: (615) 741-3054
Philip.Bangle@ag.tn.gov

Counsel for Plaintiff State of Tennessee

W. Gary Blackburn
Bryant B. Kroll
The Blackburn Firm, PLLC
213 Fifth Avenue North, Suite 300
Nashville, TN 37219
Tel: (615) 254-7770
Fax: (615) 895-7272
gblackburn@wgaryblackburn.com
bkroll@wgaryblackburn.com

Jeffery S. Roberts
Jeffery S. Roberts and Associates, PLC
213 Fifth Avenue North, Suite 300
Nashville, TN 37219
Tel: (615) 425-4400
Fax: (615) 425-4401
jeff@middletninjury.com

Counsel for Relators Mary Butner and Dana Brown

Don McKenna
Randi McCoy
Hare, Wynn, Newell & Newton, LLP
2025 Third Avenue, N Suite 800
Birmingham, AL 35203
Tel: (205) 328-5330
Fax: (205) 324-2165
don@hwnn.com
randi@hwnn.com

Irwin B. Venick
Dobbins, Venick, Kuhn & Byassee, PLLC
210 25th Avenue, N Suite 1010
Nashville, TN 37203
Tel: (615) 321-5659
irwinv@dvlawfirm.com

Randi McCoy
Hare, Wynn, Newell & Newton, LLP
2025 Third Avenue, N. Suite 800
Birmingham, AL 35203
Tel: (205) 328-5330
Fax: (205) 324-2165
Randi@hwnn.com

Counsel for Relator Suzanne Alt

Jerry E. Martin
Seth Marcus Hyatt
Barrett Johnston Martin & Garrison, LLC
Bank of America Plaza
414 Union Street. Suite 900
Nashville, TN 37219
Tel: (615) 244-2202
Fax: (615) 252-3798
jmartin@barrettjohnston.com
shyatt@barrettjohnston.com

Counsel for Relator Jennifer Pressotto

Amy L. Easton
Colette G. Matzzie
Phillips & Cohen LLP
2000 Massachusetts Ave. NW
Washington, DC 20036
Tel: (202) 833-4567
Fax: (202) 833-1815
cmatzzie@phillipsandcohen.com
aeaston@phillipsandcohen.com

Emily Stabile
Phillips & Cohen LLP
100 The Embarcadero, Suite 300
San Francisco, CA 94105
Tel: (415) 836-9000
estabile@pcsf.com

Michael Kanovitz
Loevy & Loevy
311 N Aberdeen Street Third Floor
Chicago, IL 60607
Tel: (312) 243-5900
Fax: (312) 243-5902
mike@loevy.com

Richard A. Fisher
Richard Fisher Law Office
1008 Tasso Road NE
Cleveland, TN 37323
Tel: (423) 479-7009
Fax: (423) 479-8282
Richardfisher4@cs.com

Counsel for Relator Allison Chancellor

Daniel T. Swanson
Jessica Jernigan-Johnson
London & Amburn, PLLC
607 Market Street, Suite 900
Knoxville, TN 37902
Tel: (865) 637-0203
Fax: (865) 637-4850
Dswanson@londonamburn.com
Jjerniganjohnson@londonamburn.com

Counsel for Defendant Russell S. Smith, D.C.

O. Stephen Montagnet, III
Zachary M. Bonner
McCraney, Montagnet, Quin, & Noble, PLLC
602 Steed Road, Suite 200
Ridgeland, MS 39157
Tel: (601) 707-5725
Fax: (601) 510-2939
smontagnet@mmqnlaw.com
zbonner@mmqnlaw.com

Counsel for Relators June Kimbrough and Scott Steed

Andrew F. Solinger
Jennifer L. Weaver
L. Wells Trompeter
Waller, Lansden, Dortch & Davis, LLP
Nashville City Center
511 Union Street, Suite 2700
Nashville, TN 37219
Andrew.solinger@wallerlaw.com
Jennifer.weaver@wallerlaw.com
Wells.Trompeter@wallerlaw.com

Counsel for Defendant Anesthesia Services, PLLC, d/b/a Comprehensive Pain Specialists

Edward M. Yarbrough
Justin W. Adams
Bone McAllester Norton, PLLC
511 Union St., Suite 1600
Nashville, TN 37219
Tel: (615) 238-6346
Fax: (615) 687-5787
eyarbrough@bonelaw.com
wjadams@bonelaw.com

Counsel for Defendant Steven Reid Dickerson, M.D.

Alex Fardon
Riley, Warnock & Jacobson, PLC
1906 West End Ave.
Nashville, TN 37203
Tel: (615) 320-3700
Fax: (615) 320-3737
afardon@rwjplc.com

Counsel for Defendant Gilbert Carrero, M.S.

O. Stephen Montagnet, III
Zachary M. Bonner
McCraney Montagnet Quin & Noble, PLLC
602 Steed Road, Suite 200
Ridgeland, MS 39157
Tel: (601) 707-5725
Fax: (601) 510-2939
smontagnet@mmqnlaw.com
zbonner@mmqnlaw.com

Counsel for Relators June Kimbrough and Scott Steed

/s/ Daniel J. Martin
Daniel J. Martin